e-CTA®

User Manual

Version 12.1

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e-CTA is part of Brainomix 360

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Historic revisions (https://www.brainomix.com/docs/)

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1 Introduction

1.1 Overview

Brainomix 360 e-CTA is a software medical device for processing Computed Tomography (CT) scans for stroke patients. It is supplied as a web service, with users accessing the system through a web browser on any machine with a connection to the Brainomix 360 software (e.g. a LAN or Internet connection), and may connect with other DICOM-compliant devices over a local network connection, including CT scanners and PACS systems.

Typically, brain CTA scans of stroke patients should be sent via a DICOM C-STORE operation from a CT scanner to the Brainomix 360 software. Brainomix 360 can be configured to automatically transfer the generated result series to a PACS via a DICOM C-STORE operation. Brainomix 360 may additionally be configured to send results and case reports to additional destinations, whenever a scan is processed by the software. These destinations may include Brainomix 360 Cloud or other Brainomix 360 instances, Brainomix 360 Mobile app notifications, and automatic pseudonymized email notifications with original CT and result images attached.

1.2 CTA-CS

The CTA-CS score (Tan et al., AJNR, 2009) (http://www.ajnr.org/content/30/3/525) is a scale from 0 to 3, where 0 represents no collaterals in the area affected by the stroke, and 3 indicates excellent collaterals.

CTA-CS	Description
0	No collaterals (collateral supply filling less than 10% of affected MCA territory compared to contralateral hemisphere)
1	Poor collaterals (collateral supply filling between 10% and 50% of affected MCA territory compared to contralateral hemisphere)
2	Good collaterals (collateral supply filling between 50% and 90% of affected MCA territory compared to contralateral hemisphere)
3	Excellent collaterals (collateral supply filling greater than 90% of affected MCA territory compared to contralateral hemisphere)

Note that some of these thresholds, in particular the 10% and 90% thresholds, are different from those originally described in the Tan et al. paper, where corresponding thresholds of 0% and 100% were used instead. However, the modified thresholds are more practical to enable use of the CTA-CS 0 and 3 scores on real CTA scans.

The phase of CTA image acquisition on single-phase baseline CTA is assessed in accordance with the methodology used by Rodriguez-Luna et al. (http://stroke.ahajournals.org/content/45/3/734.long), described in the table below. The phase (early arterial, peak arterial, equilibrium, peak venous, late venous) is determined by evaluating Hounsfield units (HU) on the contralateral (unaffected)

vasculature at the MCA M1 branch and straight sigmoid sinus vein. The contralateral vasculature was chosen to measure the HU to minimize the potential impact from any proximal occlusion on the ipsilateral side.

CTA acquisition phase	Arterial HU	Venous HU
Early arterial	Higher than venous vasculature	Less than or equal to 190
Peak arterial	At least 100 higher than venous vasculature	Greater than 190
Equilibrium	Less than 100 higher than, or equal to, venous vasculature	Greater than 190
Peak venous	Greater than 190	Higher than arterial vasculature
Late venous	Less than or equal to 190	Higher than arterial vasculature

Multi-phase CTA scans, when processed on a multi-phase CTA workflow, use information from all available phases to provide a single result for the entire vasculature with visualisation of peak bolus arrival time.

1.3 Multi-phase collateral scoring (mCTA-CS)

When a multi-phase CTA scan has been performed, a more fine-grained collateral score may be computed. The mCTA-CS score is a scale from 0 to 5 that takes into account both extent and delay of collaterals. The mCTA-CS is derived from Menon et al., Radiology 2015 (https://doi.org/10.1148/radiol.15142256). The higher score is defined for early and complete or nearly complete (≥90%) extent of vessels enhancement. The extent is expressed as a percentage of affected MCA territory compared to the contralateral hemisphere.

mCTA-CS	Vessels extent				
Phase delay	**<15%**	**<30%**	**<75%**	**<90%**	**≥90%**
0	0	1	3	4	5
1	0	1	2	3	4
2	0	1	2	2	3

1.4 Large vessel occlusion (LVO) detection

Brainomix 360 e-CTA will attempt to detect large vessel occlusions in brain CTA images. The software will attempt to find occlusions in the ICA-T, MCA M1 and proximal MCA M2 arteries. Note that the software will not attempt to detect occlusions in other vessels, such as the ACA or posterior arteries. Positive detections will be highlighted on the image viewer (see e-CTA display for details).

It is important to note that the software may generate false positives (highlighting an occlusion where there is none) and false negatives (failing to highlight an occlusion that is present in the image), and results must be manually verified.

2 Intended Use

This section contains important safety information regarding the usage of Brainomix 360 e-CTA

Brainomix 360 e-CTA is an image processing software package to be used by trained professionals, including stroke physicians, neurologists, and radiologists, for decision support. The software runs on standard “off-the-shelf” hardware (physical or virtualized). Data and images are acquired through DICOM compliant imaging devices. This includes DICOM files uploaded through a web browser interface.

Brainomix 360 e-CTA provides both analysis and viewing capabilities for brain CT Angiography datasets of stroke patients. The analysis capabilities are for detection of changes in the image related to acute stroke, including assessment of collateral status, and visualization of these changes.

2.1 Indications

1. Brainomix 360 e-CTA is indicated as an aid to assess the presence or absence of intracranial arterial occlusion.
2. Brainomix 360 e-CTA is indicated for use on contrast enhanced CT Angiography scans for these patients as a decision support tool, providing automated image analysis, scoring the extent of collaterals and identifying large vessel occlusion.

2.2 Contraindications

- Brainomix 360 e-CTA is not suitable for use on brain scans containing evidence of haemorrhage (intracranial, sub-arachnoid, etc).
- Brainomix 360 e-CTA is not suitable for use on patients with posterior circulation stroke.
- Brainomix 360 e-CTA is not suitable for use on images that contain coils, shunts, embolization or movement artifacts.
- Brainomix 360 e-CTA is not suitable for use on brain scans displaying neurological pathologies other than acute ischaemic stroke, such as tumours or abscesses.
- Brainomix 360 e-CTA is not intended to be used for analysing CTA images in intracranial vascular pathologies such as arterial aneurysms, arteriovenous malformations or venous thrombosis.

2.3 Warnings

⚠	Brainomix 360 e-CTA should not be used as sole basis for diagnosis. The output should not be considered as a definitive diagnosis. Brainomix 360 e-CTA should only be used by a trained professional with an understanding of CT image interpretation, as an aid to interpret images for estimation of collateral status.
⚠	Brainomix 360 e-CTA should only be used by professionals who have received adequate training on the use of the software by qualified trainers of Brainomix or authorized third parties.

⚠	Before evaluating the processing results, the accuracy of the collateral status should be reviewed. If there is any disagreement or concern with the quality of the collateral score, users should either manually edit or disregard the results.
⚠	Brainomix 360 e-CTA may not correctly identify collaterals in every scan, and may generate false positives or false negatives. The users should use their own expertise in CTA image analysis to verify that the software's output is correct.
⚠	Brainomix 360 e-CTA is not intended for primary interpretation of CT images. It is used to assist physician evaluation.
⚠	Brainomix 360 e-CTA should only be installed within a secure network which is subject to appropriate protective measures including antivirus, antimalware and firewall protection.
⚠	To minimise the risk of unauthorised use of Brainomix 360 e-CTA, users should not share access credentials and should log-out when not using the system.
⚠	Users accessing the Brainomix 360 e-CTA web user interface must ensure that they perform any analysis or diagnostic image review using an approved radiology viewing display.
⚠	Brainomix 360 e-CTA is not intended for diagnostic image review when accessed from mobile devices.
⚠	Images previewed via email are for informational purposes only and not intended for diagnostic use. Images that are previewed via email are compressed which may result in degradation of the images.
⚠	In the event Brainomix 360 e-CTA becomes partially or entirely unavailable, or if processed cases cannot be retrieved, users should rely on standard methods of image interpretation according to the standard of care.
⚠	Users should ensure that notifications are enabled on their Android or iOS mobile devices in order to receive a push notification.

⚠	A notification may not be generated or may be delayed for several reasons, including but not limited to:
	▪ Algorithmic data problems or processing errors during the analysis of scans (see Precautions for more information)
	▪ Artifacts, motion or other factors reducing registration quality
	▪ Lack of disk space to process new scans
	▪ Underlying server platform failure
	▪ Slow network connectivity
	  ▪ Slow connectivity from scanner/PACS to the Brainomix 360 server
	  ▪ Slow connectivity to the Brainomix 360 Cloud service over the internet
	▪ Delays in the Apple or Google mobile notification services
	▪ Poor signal on the receiving mobile device
	▪ Power saving modes of some mobile devices may delay notifications

2.4 Precautions

⚠	The performance of Brainomix 360 e-CTA is limited by the quality of the input CT image. If Brainomix 360 e-CTA receives poor quality, invalid or corrupted data, it may affect the system's ability to process results effectively. The user should therefore manually inspect the image for scanner artifacts and poor-quality images to avoid incorrect results. The user of e-CTA should also monitor the image quality used for automated analysis in general, e.g. concerning motion artifacts.
⚠	Brainomix 360 e-CTA is dependent on the correct functioning of the underlying server platform on which it is installed and is not intended to be used as a data store. Results and original data should be stored in a PACS system and backed up appropriately.
⚠	The user should monitor the circumstances of contrast injection, which is also mandatory for medical reasons.
⚠	Brainomix 360 e-CTA has only been validated and is intended to be used in adult patient populations. Safety and effectiveness in paediatric cases has not been established.

2.5 Clinical Benefits

The clinical benefits of e-CTA are, as follows:

- To provide a reference CTA collateral score with the sensitivity and specificity at the level of an expert.
- To support informed clinical decisions by providing fast and accurate identification and localisation of large vessel occlusions.

2.6 Use Environment

Brainomix 360 e-CTA is intended to be used on desktop or mobile devices approved by the healthcare organisation for clinical use. Both desktop and mobile view deliver benefits of the device; however, mobile preview images should not be used as an aid to diagnostic readings.

3 Installation and Training

Prior to first use of Brainomix 360 e-CTA, installation of the software and training for its user(s) are required.

3.1 Installation

Brainomix 360 e-CTA can be installed for your organisation either via a cloud-based server deployment or a local physical server installation. Prior to the installation, Brainomix (or an authorised distributor) collects all necessary installation information, including location, power and networking requirements and any third-party systems that may interact with the Brainomix 360 e-CTA software. Liaise with Brainomix or authorised distributor with regards to the method and requirements for installation.

In order to use the software on mobile devices (smart phone and tablet), download the Brainomix 360 Mobile app on your device:

- App Store (for iOS devices) (https://apps.apple.com/us/app/e-stroke-mobile/id1443749413)
- Google Play (for Android devices) (https://play.google.com/store/apps/details?id=com.brainomix.ess.android&gl=US)

Follow the instructions of your mobile device to complete the installation process.

3.2 Training

The use of Brainomix 360 e-CTA requires competency in the analysis and interpretation of brain CTA scans of patients with acute ischaemic stroke. Training in the use of the software is required prior to first use of the software. The training is organised in advance and delivered by qualified trainers of Brainomix (or third-party trainers appointed by Brainomix) at the time of the initial installation to the clinical and/or IT representative(s) of your organisation. Subsequently, new users may be trained in the use of the software by the designated lead trainer(s) of your organisation. Brainomix will communicate if any new training is required following the initial deployment. For any questions related to training, please contact the lead trainer(s) of your or organisation or contact Brainomix at support@brainomix.com (mailto:support@brainomix.com)

4 System Specifications

4.1 Server

The following should be considered minimum specifications for reliable use of the application.

Processor	x86-64 compatible processor with 4 cores at 3.0+ GHz or 6 cores at 2.4+ GHz supporting SSE4.2 instructions (e.g. Intel Core i5, i7, Xeon)
Memory	8GB
Disk	100GB
Network	1Gb Ethernet
Operating System	Ubuntu Linux 22.04

4.2 Clients

The following web browsers and platforms should be considered minimum requirements for reliable operation of the web user interface.

Web Browser	Supported Version
Google Chrome	Latest version
Mozilla Firefox	Latest version
Microsoft Edge	Latest version
Mobile Safari (iOS)	Latest version

Platform	Minimum Specifications
PC (desktop or laptop)	Memory: 4GB RAM Screen size: 13.3 inches and above Screen resolution: 1024 x 768 Processor: Intel or AMD CPU
iPad	Memory: 2GB RAM Screen size: 9.4 inches and above Screen resolution: 2048 x 1536
Mobile phone (iPhone or Android)	Memory: 2GB RAM Screen size: 4.7 inches and above Screen resolution: 1334 x 750

4.3 Languages

The following languages are supported in the current version of the software.

- Bulgarian (bg)
- Czech (cs)
- Welsh (cy)
- German (de)
- Greek (el)
- English (en)
- Spanish (es)
- Finnish (fi)
- French (fr)
- Croatian (hr)
- Hungarian (hu)
- Italian (it)
- Latvian (lv)
- Lithuanian (lt)
- Dutch (nl)
- Polish (pl)
- Portuguese (pt)
- Portuguese (Brazil) (pt-br)
- Romanian (ro)
- Serbian (sr)
- Slovak (sk)
- Slovenian (sl)
- Swedish (sv)
- Turkish (tr)

4.4 Performance and Lifetime

The following performance specifications apply to the current version of the software.

Process time (per CT scan)	≤ 2 minute (after retrieval from the PCS or from upload completion)
LVO Detection Sensitivity	Proximal occlusions (ICA-T/M1) > 85%
LVO Detection Specificity	Proximal occlusions (ICA-T/M1) > 90%
Collateral Score agreement with experts	Intraclass correlation coefficient > 70%
Sensitivity for detection of favourable collateral flow (CS 2-3)	> 65%
Specificity for detection of favourable collateral flow (CS 2-3)	> 90%

A separate technical data sheet for the Brainomix 360 platform with information relevant for your organization's IT department is provided at the time of first installation and is available upon request.

The product lifetime of Brainomix 360 e-CTA is indefinite for the current software version and for the duration of the contracted service provision when deployed on a virtual machine that receives regular software updates from Brainomix.

5 Scanner and Image Compatibility

The Brainomix 360 e-CTA software is designed to work with contrast-enhanced CT scans sent via the DICOM protocol. These scans should have the following characteristics:

Slice thickness	1mm maximum slice thickness
Acquisition volume	Full brain acquisition (e.g. arch-to-vertex in a single sequence, or cerebrum sequence)
Reconstruction method	Filtered back projection (FBP) with a moderate filter kernel (i.e. no excessive sharpening or smoothing).
Bolus timing	Peak arterial or equilibrium phase (good acquisition timing) preferred

Use of thicker slices or other reconstruction methods (e.g. iterative reconstruction) can lead to the introduction of image artifacts, and consequently reduced scoring performance.

Cropped acquisition (e.g. missing top part of the skull) can reduce scoring performance.

If the acquisition phase is too early, the contrast will not have had time to reach all areas of the brain tissue and results may be computed incorrectly. Likewise, if the acquisition phase is too late, the contrast in arteries may be too low for the software to compute results accurately.

6 Cybersecurity

Brainomix 360 e-CTA is installed on a server (either physical or virtual) within the hospital network and as such is potentially vulnerable any malware or viruses penetrating the hospital network in which Brainomix 360 e-CTA is embedded, or to any other form of unauthorized access.

Brainomix 360 e-CTA does not present a specific vulnerability to the hospital network in which it is embedded and is unlikely to be intentionally exploited. However, should such risks occur, they could potentially result in corruption or loss of processing data being received, stored or sent, corruption, loss or damage to stored configuration data or interruption or prevention of normal operation.

Brainomix 360 e-CTA has been designed and developed with features and requirements to mitigate these cybersecurity risks. In particular the system has been designed such that:

- User access can be restricted and controlled
- Data storage components are not accessible over a network other than through Brainomix web-service components
- Only the minimum number of ports required for all functionality are left open
- Data transmission across untrusted connections is secured and encrypted
- Brainomix can remotely monitor the system and securely install security updates as needed

Brainomix 360 e-CTA has been designed to employ a layered authorization model based on user roles. This includes standard users who access and use the system and Administrators who have additional privileges to enable them to:

- Access patient data or system configuration
- Set and manage security options
- Delete patient data/scans
- Modify or remove users

The installation package for Brainomix 360 e-CTA includes local firewall, antivirus and antimalware protection for the server. These can be changed or amended to suit local security policies; however, it is important that Administrators contact Brainomix support before removing or re-configuring these default protections to avoid compromising the security of the system.

To prevent unauthorized access, Brainomix 360 e-CTA includes inbuilt username/password and two-factor authentication mechanisms which are described in the Access Control section of this user manual.

If users or administrators suspect that a user's log-on credentials have been compromised, the password should be changed immediately, or the account disabled.

Passwords can be set and re-set by users and/or administrators but must meet minimum password complexity requirements. Minimum password complexity requirements are set to a default but can be configured by Administrators to facilitate options for more complexity where this is required or mandated by local security policies.

These options include setting the mandatory use of special characters, creating blacklists of passwords which may not be used and setting the maximum age for re-setting passwords. Two-factor authentication is optional by default but may also be enforced by Administrators.

Brainomix 360 e-CTA can be set to automatically disable user accounts that have had no activity for a defined period and, for active users, also includes an automatic time-out feature which will log out users after a period of inactivity.

To minimize the risk of unauthorized use of Brainomix 360 e-CTA, users should not share access credentials and should log-off immediately when not using the system.

Administrators can also opt to use Active Directory user accounts (via LDAP) in place of the default Brainomix authentication system.

Although various cybersecurity measures have been designed and implemented, the successful mitigation against security vulnerabilities for Brainomix 360 e-CTA depends on the security infrastructure of the hospital network environment, best practice by users and management by Administrators.

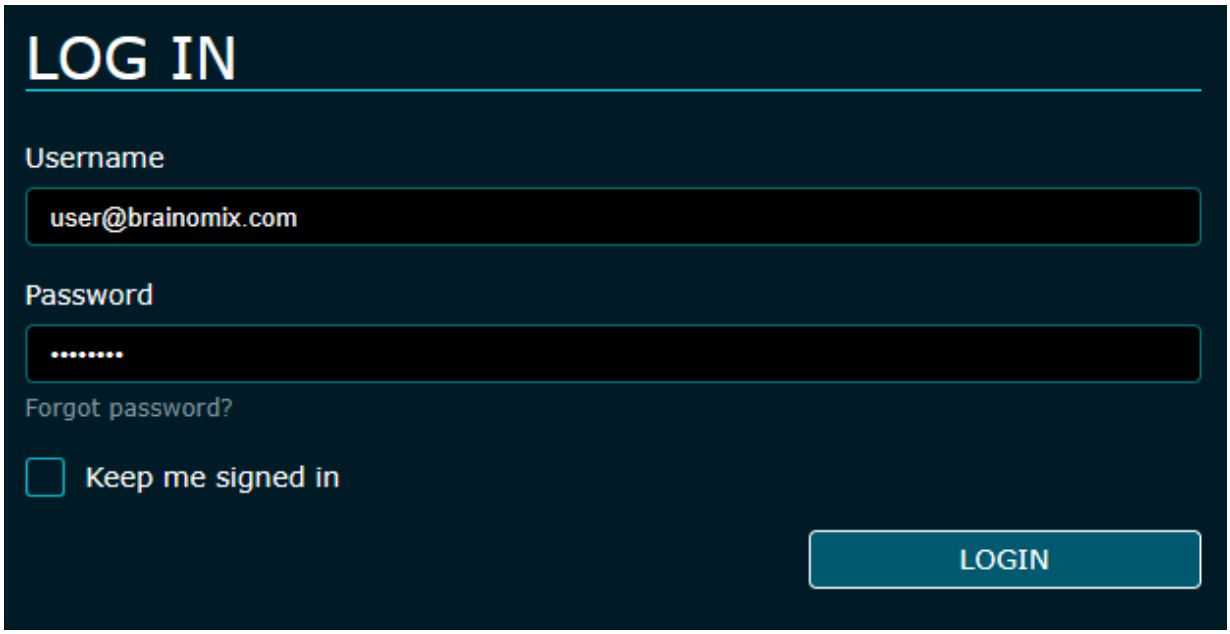
Brainomix 360 e-CTA should only be installed within a secure hospital network which is protected by a network level firewall, antivirus and antimalware software and, ideally, Intrusion Detection Software (IDS).

Client machines used to access the server hosting Brainomix 360 e-CTA should also be protected by antivirus/antimalware software and IDS and should be kept up to date with security patches and updates.

7 Access Control and Notifications

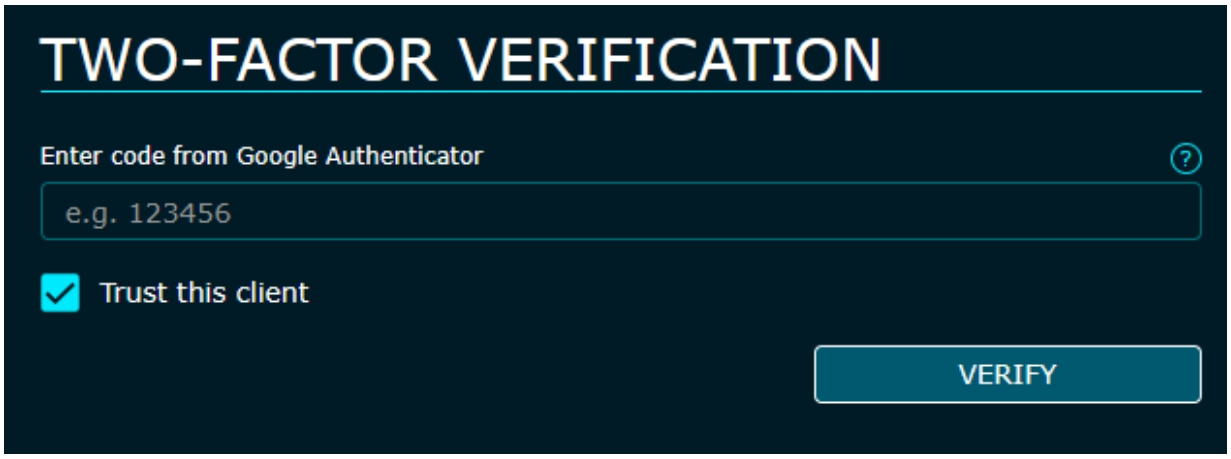
7.1 Logging In

1. Go to the Brainomix 360 or Brainomix 360 Cloud server address in your web browser.
2. You will be prompted to log in if you have not used the application recently from your current web browser. Your system administrator can provide login credentials.
   Brainomix 360:



   Brainomix 360 Cloud:

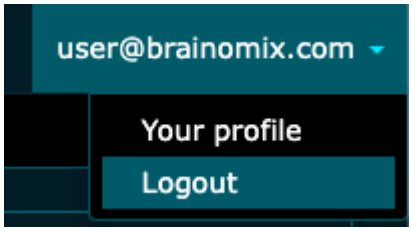
   1. If logging into Brainomix 360 Cloud, enter your organisation ID
   2. Enter your username
   3. Enter your password
   4. Leave the box unchecked if you want to be automatically logged out after 1 hour, or when you quit the browser. Check the box if you want to remain signed in on this computer until you sign out.
   5. Click the submit button or press enter
3. If you have forgotten your password, you can request a password reset email by clicking the "Forgot password?" text.



4. If you have enrolled in two-factor authentication, you may be prompted to enter a token code from your authenticator app.
    - Select "Trust this client" to avoid being asked for a token code again on this device or browser. Do not use this option on shared devices.
    - If you cannot get a token code from your authenticator app, you can enter an unused recovery code from the list given when enrolling in two-factor authentication.

7.2 Logging Out

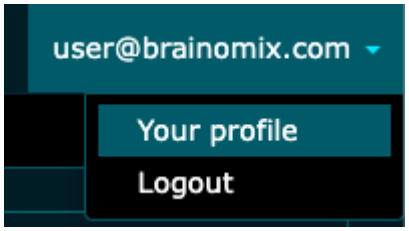
1. Select your username at the right hand side of the navigation bar



2. Click **Logout**

7.3 Changing Your Password

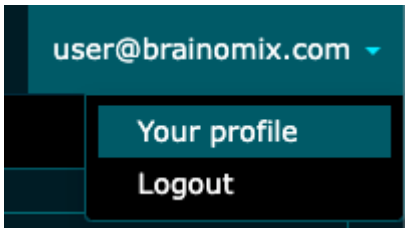
1. Select your username at the right hand side of the navigation bar



2. Click **Your profile**
3. Click on the tab labelled **Change password**
4. Enter your old and new passwords (Passwords must meet minimum complexity requirements: 8 characters with at least one number and letter.)
5. Click **Save** or press enter

7.4 Two-factor authentication

1. Select your username at the right hand side of the navigation bar



2. Click **Your profile**
3. Click on the tab labelled **Two-factor authentication**
4. Click the **enroll** button.
5. Follow the on-screen enrollment instructions.

7.5 Phone Directory

Access

1. The phone directory can be accessed at all times through the app and the desktop user interface if any users in your organisation have phone numbers saved.

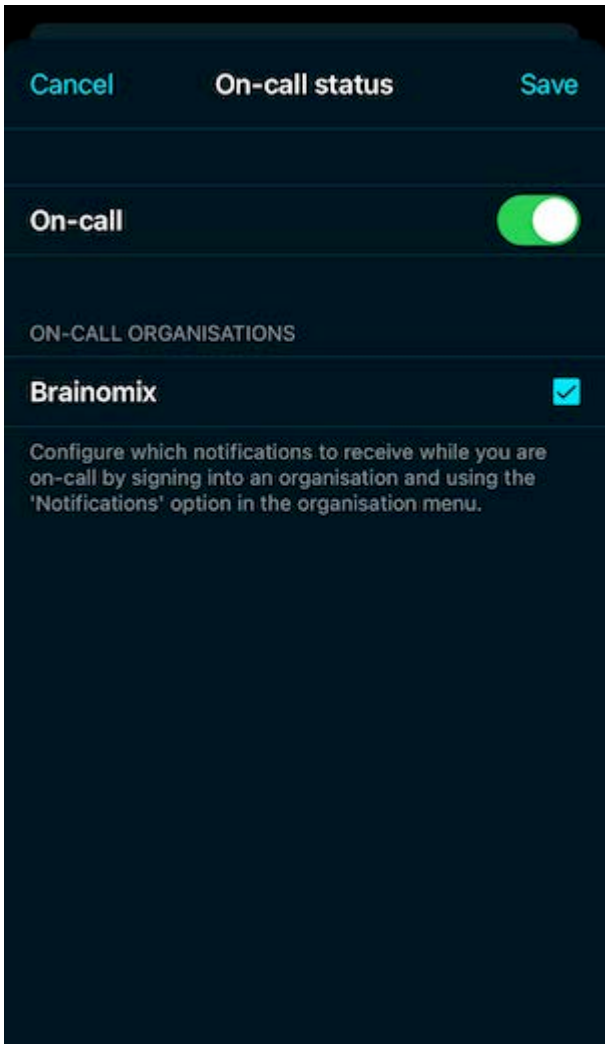
Usage

1. All users and entries with an assigned phone number are displayed and can be called.
2. On launching a call to another user, the call is logged and can be viewed in the user profile for both users.
3. If the phone directory is launched from a case, any calls made are logged as being part of the case and the calls will appear in the case messaging history.

7.6 On-Call Status

Configuration

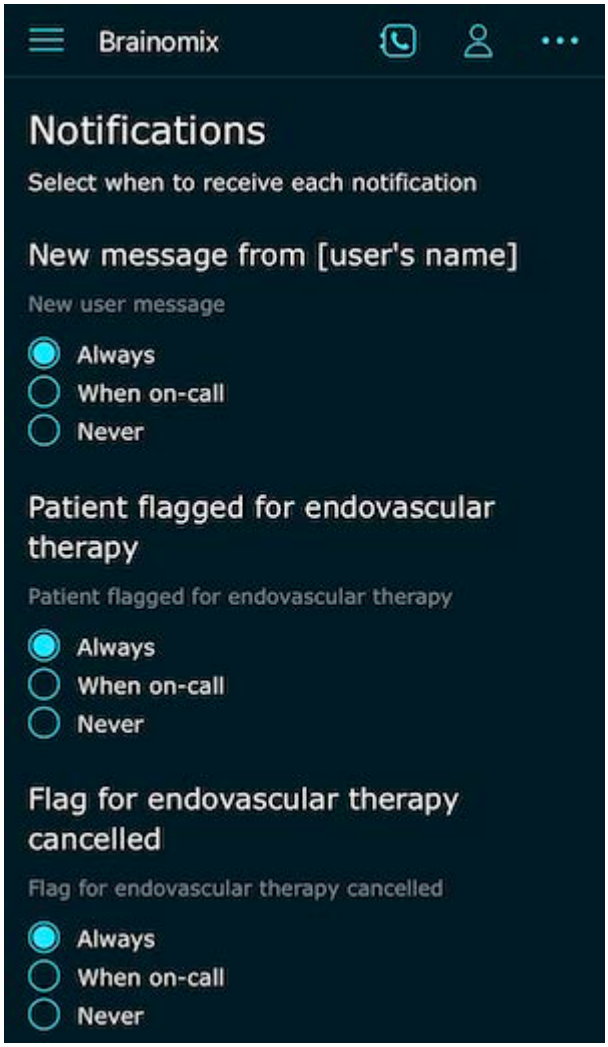
1. Your on-call status can be configured through the app. You can choose to be on-call or not, and which organisations you are going to be on-call for.



7.7 App Notifications

1. You can choose to always receive notifications, only receive them when you are on-call for an organisation, or never receive them.

2. These settings can be configured by tapping 'Notifications' in the app menu for an organisation.



In order to receive notifications from the Brainomix 360 Mobile app, you must ensure that notifications are enabled on your mobile device. This can be done at the time of the installation of the Brainomix 360 Mobile app on your mobile device or can be set later following the below steps.

iOS

- Launch the Settings app.
- Tap Notifications.
- Scroll to Brainomix 360 Mobile > Tap.
- Toggle the **Allow Notifications** switch to **On** to enable notifications.
- Toggle the **Time-Sensitive Notifications** switch **On** (notifications are always delivered immediately and remain on the Lock Screen for an hour).
- Choose your alert preferences - it is recommended to select all (Lock Screen, Notification Centre and Banners) and set the **Banner Style** to **Persistent**.
- Toggle the **Sounds and Badges** switches to **On** (recommended).

Android

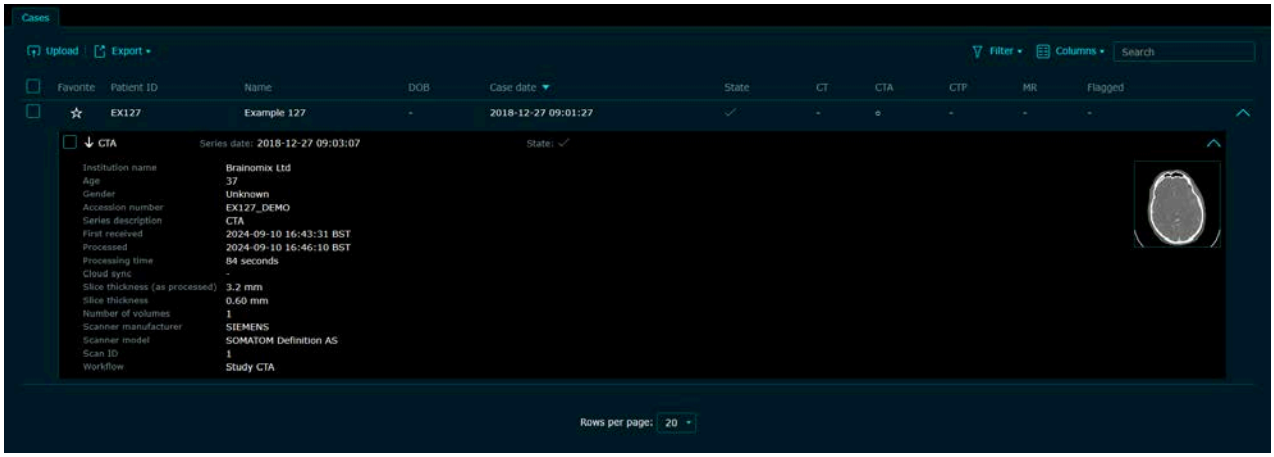
- Launch the Settings app.
- Tap Apps.
- Scroll to Brainomix 360 Mobile > Tap.
- Tap Notifications.
- Toggle the **Allow notification** switch to **On** to enable notifications, including messages, sounds and vibration.
- Toggle the **Show silently** switch **Off** (recommended).

- Toggle the **Set as priority** switch **On** to turn on the screen while "Do not disturb" is turned on (recommended).

8 The Case List

8.1 Overview

Standard usage

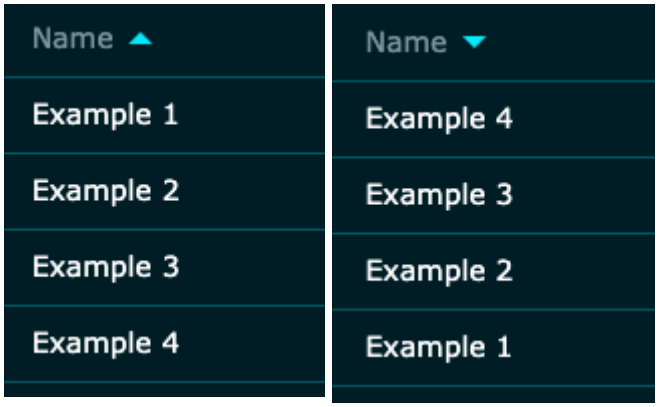


- The case list page shows all cases available to you. By default, they are listed in order of the latest case date. Cases being processed will show a percentage completed in the State column.
- Move through the pages of cases by clicking on the page numbers below the list.
- Click on a case to open it in the case viewer (see the Case Viewer section).
- If you or someone else in your organisation has already viewed a case, the score will be displayed at the end of its row.
- Click on the ⌄ icon to expand the case details and expand each scan to see scan details and a preview thumbnail of the scan.
- To customise the displayed columns, click on the "Columns" button. An administrator can change the default set of columns for your organisation.

8.2 Finding Cases

Sorting

Sort the case list by clicking on the required column heading; click on the title again to reverse the order, as shown below:



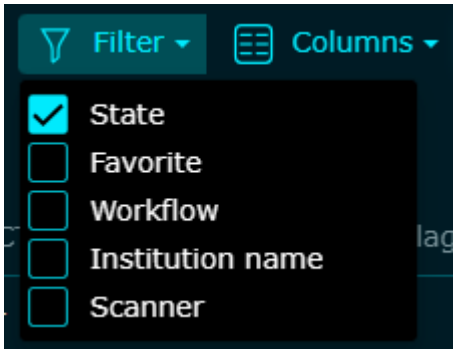
Search

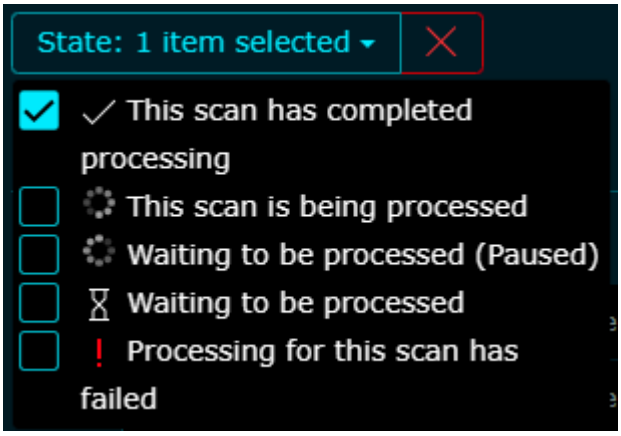
Search for a patient by name, accession number or ID by entering text into the search box above the table.

Results will be displayed in a pop-up section as you type. The case list will update to show the results when the Enter key is pressed.

Filtering

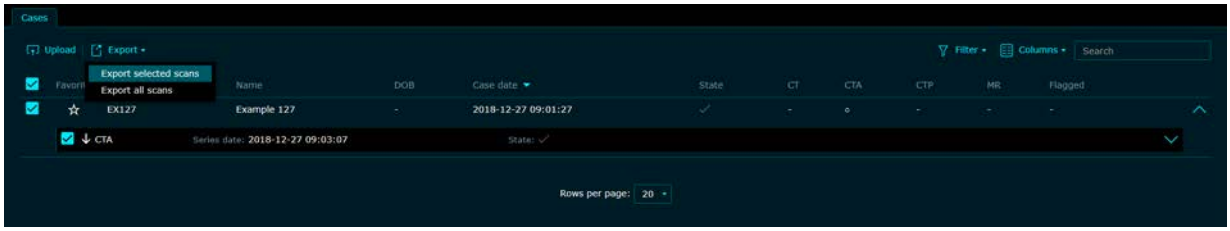
Filter the cases using the available options. Once the option is selected, choose the values to filter by in the dropdown. If any scan in a case matches the selection, all scans in the same case will be shown.





8.3 Exporting Results

1. Select all the cases you wish to include by clicking on their tick-boxes. Repeat for all relevant pages of the list.



   Tip: To select all the cases on a page, click the tick-box in the header row.
   Tip: You can change the "rows per page" setting at the bottom of the table to view more scans on each page.
   Tip: You can open a case and select only some scans within the case if you want to export them.
2. Click on the **Export** button, and choose to export only the selected scans, or all scans on all pages.
3. Click the appropriate button in the window to export in CSV or XLSX format.
   - These file types can be opened in a variety of applications, including Microsoft Excel.
   - The downloaded files contain a row for each case with identifying information, scoring results, and instructions on how to interpret the exported information.

9 The Case Viewer

9.1 Case Overview

The case viewer contains all the information for a given case. Each primary scan in the case will be displayed in a separate tab.

Patient Details

This section at the top summarises the personally identifying information for the patient. These details are taken from the source DICOM series tags. Note that this information may have been removed if the case has been pseudonymized, e.g. if it has been received by peer-to-peer sync or you are viewing the case on Brainomix 360 Cloud.

Additional Scans

Additional scans or DICOM series may be linked to the case if CT viewer or DICOM storage workflows have been configured. These can be accessed from the Report tab.

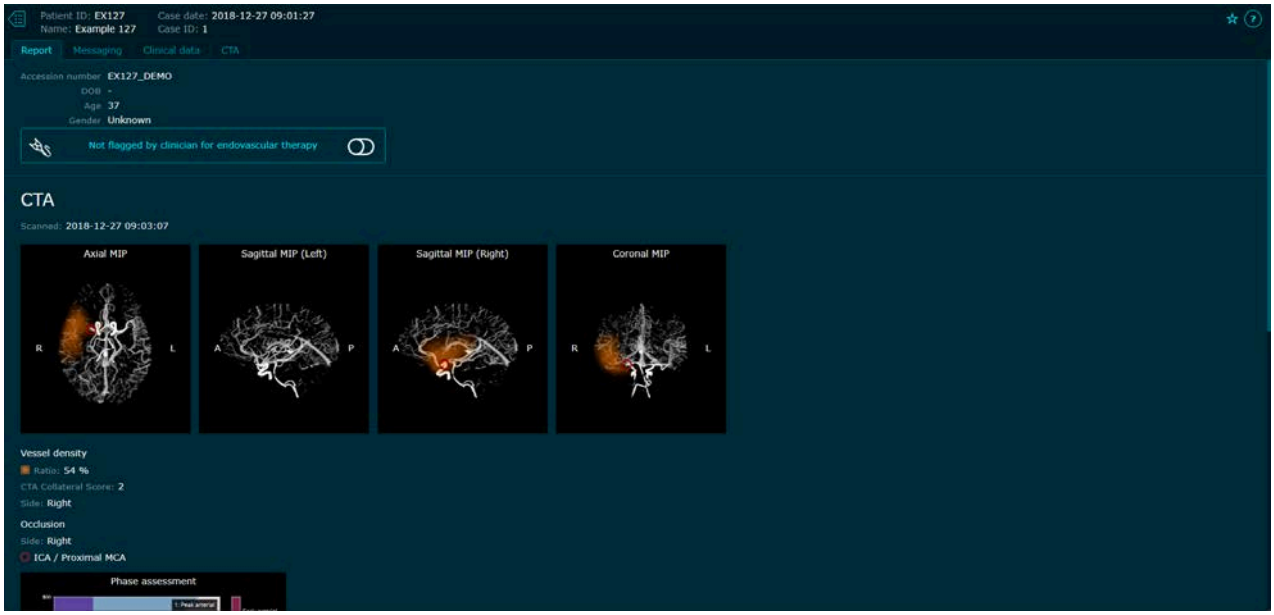
9.2 Report

The Report includes an imaging summary of all imaging modalities for a patient, which can be sorted using the sort options. Each displayed slice in the case report is a link to the full slice viewer for the relevant scan.

The results from each primary scan are displayed under the imaging summary.

The detailed information for every scan in the case is displayed after the imaging summaries.

You can download a PDF report of the case, or email the PDF report of the case to specific email addresses if configured.



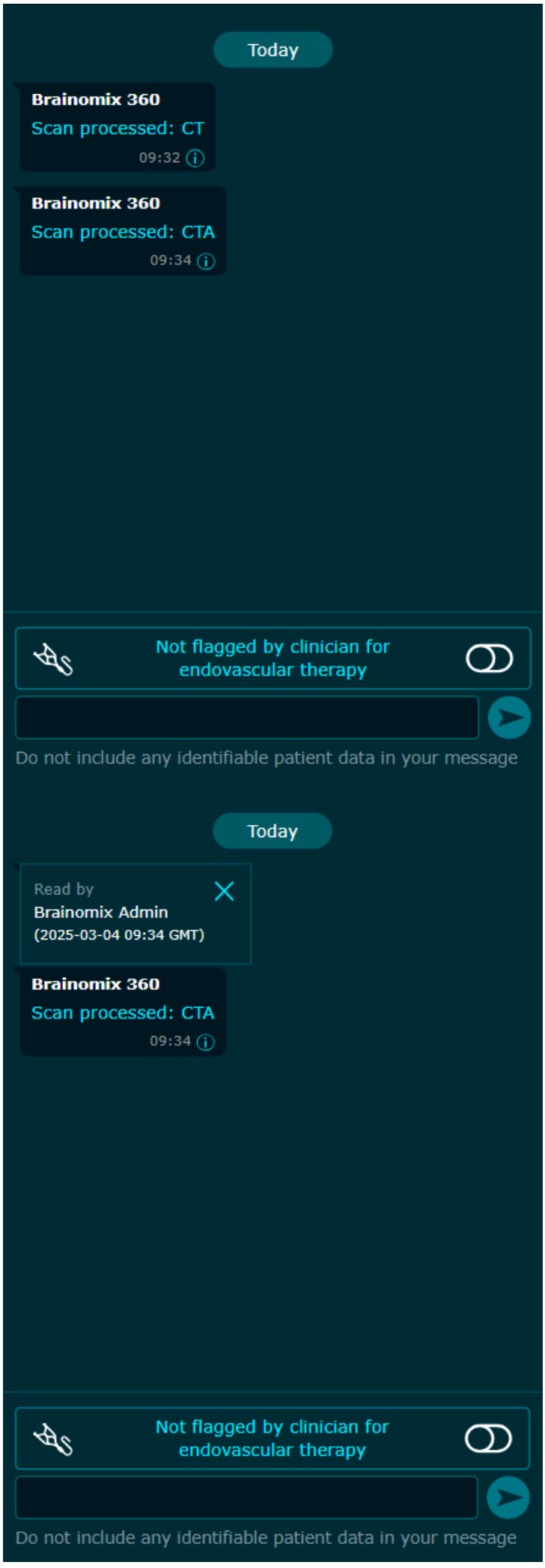
9.3 **Messaging**

If enabled by your system administrator, messages can be viewed and sent for a case. As new messages arrive they can be viewed in the case and if configured, a mobile app notification will be sent to all registered users.

New messages will appear at the bottom of the chat area as they are received.

To send a message, type in the box at the bottom, and click the send button to the right.

To see who has viewed a message, press and hold the message. You can also click the info icon to view the list. To close the list, click the close icon.


Today
Brainomix 360
Scan processed: CT
09:32
Brainomix 360
Scan processed: CTA
09:34
Not flagged by clinician for endovascular therapy
Do not include any identifiable patient data in your message
Today
Read by
Brainomix Admin
(2025-03-04 09:34 GMT)
Brainomix 360
Scan processed: CTA
09:34
Not flagged by clinician for endovascular therapy
Do not include any identifiable patient data in your message

9.4 Flag a patient for endovascular therapy

If messaging functionality is enabled by your system administrator, you can flag a patient for endovascular therapy from the report and from the messaging tab.

Select the organisations to flag the patient to and confirm the flag. Any users at the selected organisations with endovascular therapy notifications configured will be notified that the patient has been flagged.

The flag can be cancelled if required, and any users at the selected organisations with cancelled endovascular therapy notifications configured will be notified that it has been cancelled.

9.5 Clinical data

If enabled by your system administrator, the clinical data section will be available in a separate tab. This can be used to save extra clinical data for the patient. All previously saved clinical data can be viewed by clicking "View history".

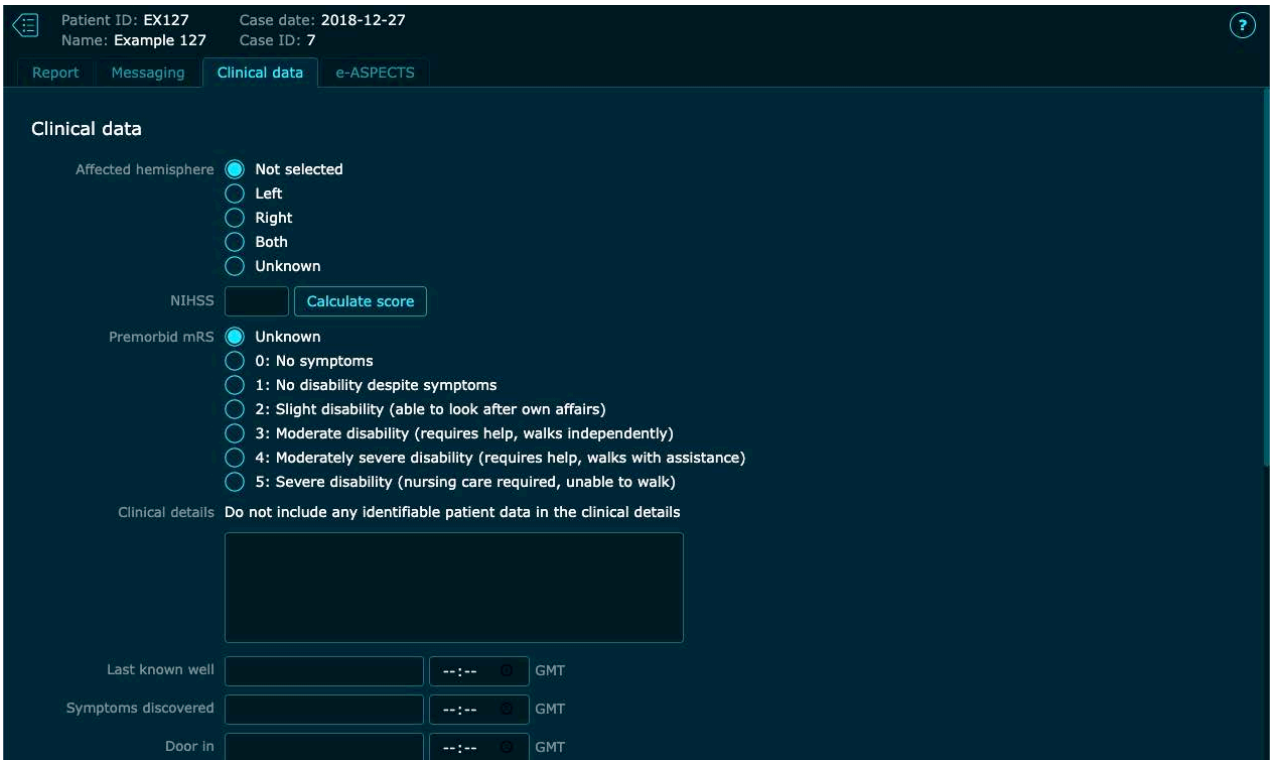
The affected side from clinical presentation can be entered here, and if it is different to the automatically detected side then the results will be updated to use the clinical side.

A pre-calculated total NIHSS score can be entered directly, or you can calculate it interactively by clicking "Calculate score" and entering the score for each item into the form.

All the other clinical data fields can be edited to add the clinical information or left blank if they are not relevant.

The NIHSS score after 24 hours can be added after all the other fields, in the same way as above.

The clinical data entered here will be included in PDF case reports and exported CSV/XLSX spreadsheets.



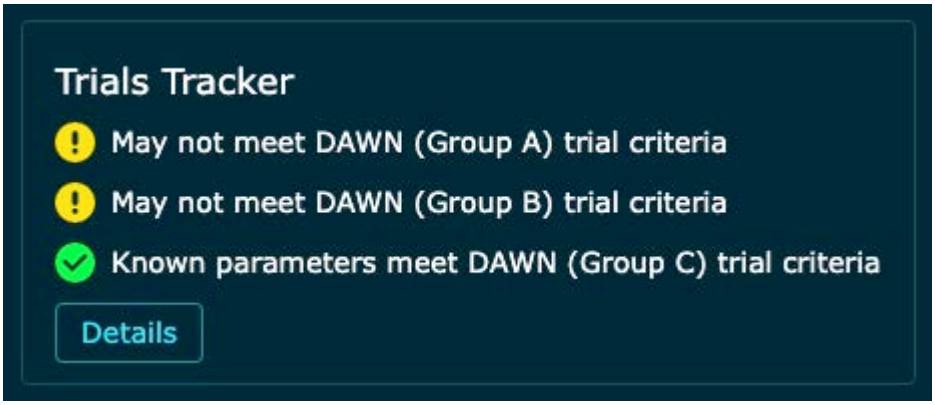
9.6 Clinical trials

If enabled by your system administrator, the patient's eligibility for clinical trials is assessed and reported in the web user interface and PDF case reports.

By default, criteria for the DAWN, DEFUSE-3, ESCAPE, EXTEND trials and ESO guidelines for late time window are available for system administrators to enable.

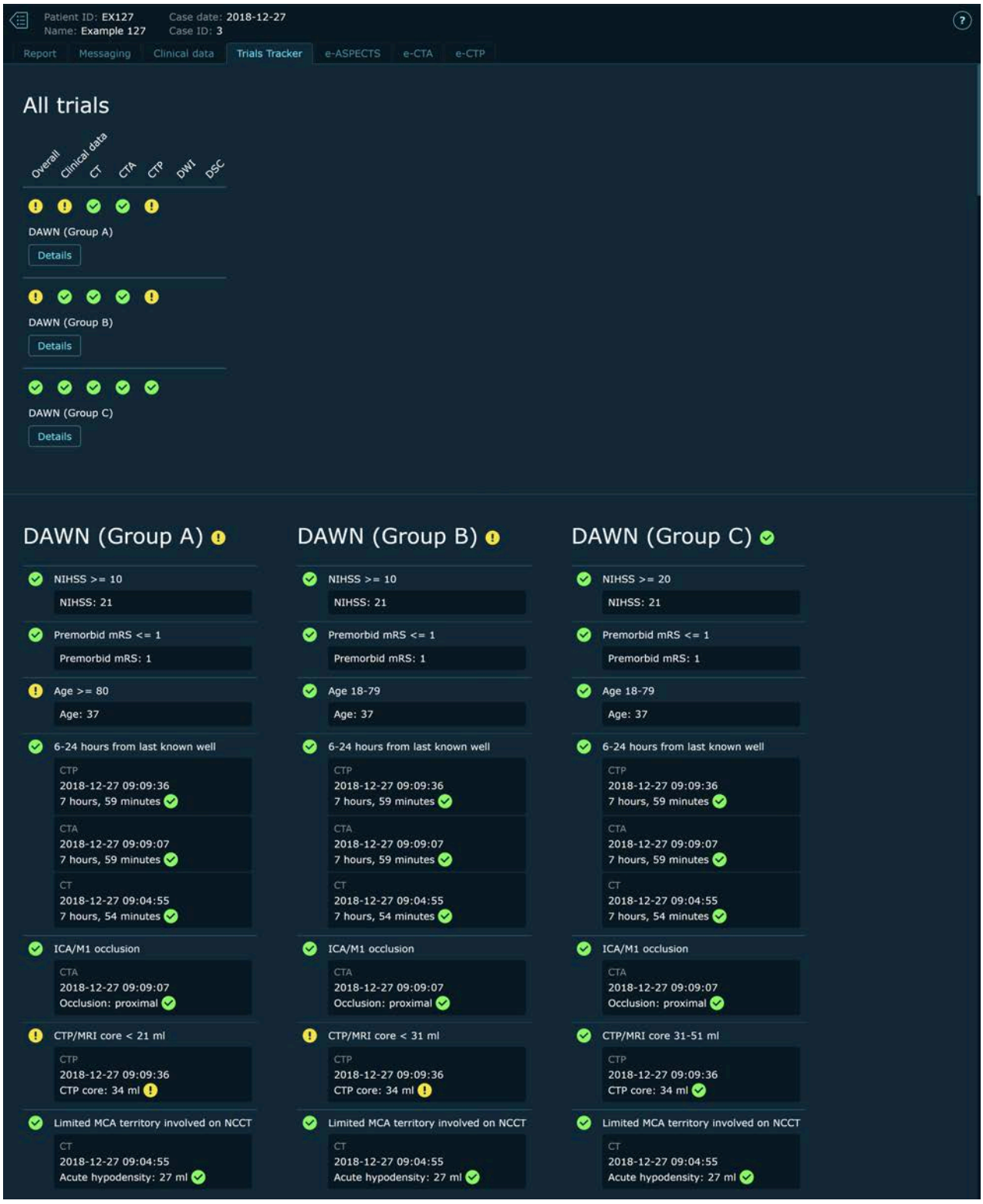
A summary of the patient's eligibility for the configured clinical trials is displayed at the top of the clinical data tab.

Only the selected base scans for the patient are used to determine eligibility for the configured trials.



Eligibility for each criterion is determined by automatic imaging results for each scan and clinical data if provided. For perfusion core assessment, the volume of the core map is used.

More detail about the eligibility of the patient for each criteria within each trial is available on the clinical trials tab.


Patient ID: EX127
Name: Example 127
Case date: 2018-12-27
Case ID: 3
Report
Messaging
Clinical data
Trials Tracker
e-ASPECTS
e-CTA
e-CTP
All trials
Overall
Clinical data
CT
CTA
CTP
DWI
DSC
DAWN (Group A)
Details
DAWN (Group B)
Details
DAWN (Group C)
Details
DAWN (Group A)
NIHSS >= 10
NIHSS: 21
Premorbid mRS <= 1
Premorbid mRS: 1
Age >= 80
Age: 37
6-24 hours from last known well
CTP
2018-12-27 09:09:36
7 hours, 59 minutes
CTA
2018-12-27 09:09:07
7 hours, 59 minutes
CT
2018-12-27 09:04:55
7 hours, 54 minutes
ICA/M1 occlusion
CTA
2018-12-27 09:09:07
Occlusion: proximal
CTP/MRI core < 21 ml
CTP
2018-12-27 09:09:36
CTP core: 34 ml
Limited MCA territory involved on NCCT
CT
2018-12-27 09:04:55
Acute hypodensity: 27 ml
DAWN (Group B)
NIHSS >= 10
NIHSS: 21
Premorbid mRS <= 1
Premorbid mRS: 1
Age 18-79
Age: 37
6-24 hours from last known well
CTP
2018-12-27 09:09:36
7 hours, 59 minutes
CTA
2018-12-27 09:09:07
7 hours, 59 minutes
CT
2018-12-27 09:04:55
7 hours, 54 minutes
ICA/M1 occlusion
CTA
2018-12-27 09:09:07
Occlusion: proximal
CTP/MRI core < 31 ml
CTP
2018-12-27 09:09:36
CTP core: 34 ml
Limited MCA territory involved on NCCT
CT
2018-12-27 09:04:55
Acute hypodensity: 27 ml
DAWN (Group C)
NIHSS >= 20
NIHSS: 21
Premorbid mRS <= 1
Premorbid mRS: 1
Age 18-79
Age: 37
6-24 hours from last known well
CTP
2018-12-27 09:09:36
7 hours, 59 minutes
CTA
2018-12-27 09:09:07
7 hours, 59 minutes
CT
2018-12-27 09:04:55
7 hours, 54 minutes
ICA/M1 occlusion
CTA
2018-12-27 09:09:07
Occlusion: proximal
CTP/MRI core 31-51 ml
CTP
2018-12-27 09:09:36
CTP core: 34 ml
Limited MCA territory involved on NCCT
CT
2018-12-27 09:04:55
Acute hypodensity: 27 ml

9.7 e-CTA Display

Scan Details

The scan time is located on the bottom left corner of the scan. Additional scan details are located in the Info button on the bottom toolbar, and in the Report tab. Some details are taken from the source DICOM series tags (e.g. study description) while others are derived from the software itself (e.g. algorithm version).

Detailed Results

The CTA-CS score and related information are displayed at the top of the page. This can be scrolled and contains the following information.

Warnings

If this section is visible on the left hand side of the page, there are warnings from e-CTA which may affect the accuracy of the score.

Vessel Density

This section shows the CTA Collateral Score calculated by e-CTA. The vessel density ratio on the affected side is used to calculate the CTA Collateral Score, as follows:

CTA Collateral Score	Description
0	No collaterals (collateral supply filling less than 10% of affected MCA territory compared to contralateral hemisphere)
1	Poor collaterals (collateral supply filling between 10% and 50% of affected MCA territory compared to contralateral hemisphere)
2	Good collaterals (collateral supply filling between 50% and 90% of affected MCA territory compared to contralateral hemisphere)
3	Excellent collaterals (collateral supply filling greater than 90% of affected MCA territory compared to contralateral hemisphere)

Occlusion

This section shows the detected side of the brain where the CTA Collateral Score indicates a lack of collaterals. If an LVO has been detected, the details of the vessel and the location will be displayed here. Click on the icon or the 'Show' button to jump to the slice where the occlusion has been detected.

Acquisition

This section shows the computed CTA acquisition phase for single-phase CTA scans. Possible phases (earliest to latest) include: early arterial, peak arterial, equilibrium, peak venous, and late venous. For a full definition, see section CTA acquisition phase. Scans acquired in early or late phases may lead to inaccurate collateral assessment. The AIF and VOF measurement values are displayed, and it is possible to click on the icon or 'Show' button to jump to the slice of the AIF or VOF measurement location.

Vessel MIP Images

Maximum intensity projections of the detected vascular system in axial, coronal and left and right hemisphere sagittal views are available to view, with colour coding to indicate peak bolus arrival time if the source was a multi-phase CTA scan. Switch between them using the title menu on the MIP image. You can access all the MIP images, the results scan and the unannotated scan from this menu.

An orange shaded vessel density map will be displayed as an overlay on the MIP image where the vessel density ratio is lower than the contralateral side. Stronger orange shading corresponds to a greater local decrease in vessel density. In the case of a multi-phase CTA image, the vessel density map will be displayed on the temporal MIP image.

If an LVO has been detected, its location will be displayed on these images as a red circle (or orange circle if manually edited).

Phase Assessment Graph

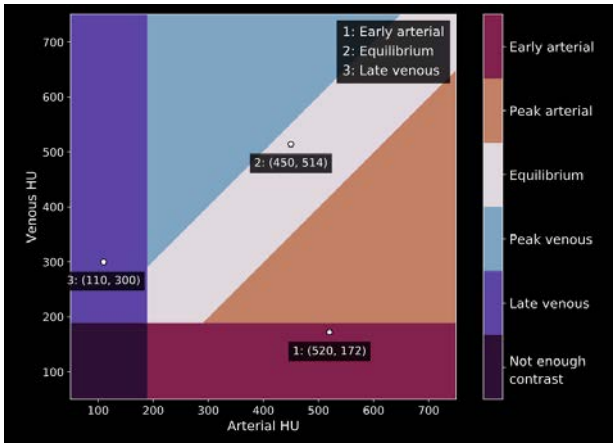
Visualisation of the CTA acquisition phases based on the AIF and VOF measurements. The acquisition phase thresholds are defined in the CTA acquisition phase section.

For best algorithm performance, AIF and VOF measurements between 400-700 HU are preferred, with higher values generally being better. Contrast levels outside this range may adversely affect algorithm performance.

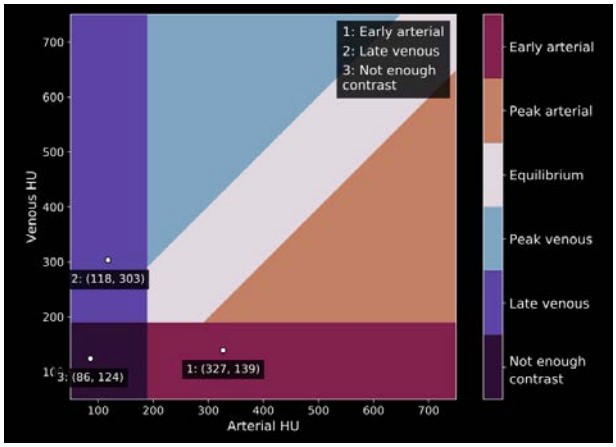
Multi-phase

The ideal three-phase multi-phase acquisition will contain an early or peak arterial phase for the first scan, followed by equilibrium or peak venous phase in the second scan, and late venous phase for the third scan.

Below is an example of a good multi-phase acquisition:



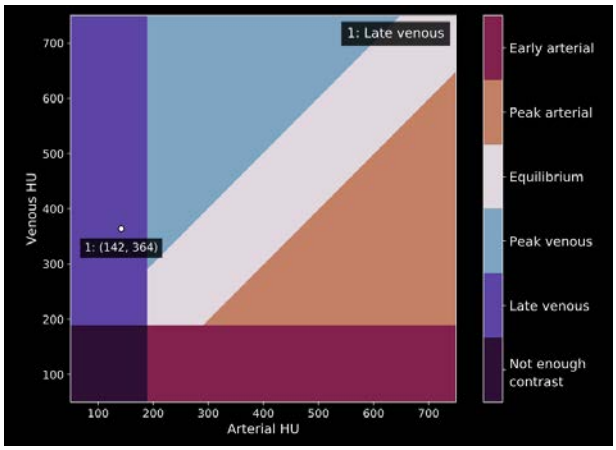
Below is an example of a multi-phase acquisition with low overall contrast levels and late acquisition of phases 2 and 3:



Single Phase

In a single-phase acquisition the best phases for occlusion detection are early and peak arterial. Vessel density can be assessed best from peak arterial and equilibrium phases. If the scan is in a venous phase or no contrast is detected, then the analysis will not be accurate.

Below is an example of a late single-phase acquisition which is likely to give inaccurate results:



Multi-phase CTA Scans

If multi-phase CTA images are available, all phases will be co-registered and processed as a single data set. Colour-coded vessels MIP images will be generated, with a colour scale indicating the peak contrast arrival time. This scale also indicates which time range the individual phases cover.

Typically, if the contrast bolus peaks in an earlier phase, it will be coloured yellow, and if the bolus peak arrives in a later phase, it will be coloured blue. As a result, for a stroke patient with an LVO, late arriving collaterals beyond an occluded vessel may be more blue-coloured, whereas on the healthy side of the brain, the vessels would typically be more yellow-coloured.

Unlike single-phase CTA results, the orange vessel density map is not shown on the colour-coded MIP images. Instead, a separate temporal MIP image is generated (without colour coding) which displays the orange vessel density map overlay.

Unannotated Scan

The Unannotated Scan view always shows the CT scan without overlays. Use this view when manually assessing a scan.

The HU value of the pixel under the mouse pointer is displayed adjacent to it on the unannotated scan. Note that CT scans contain noise, volume averaging, and other artifacts, so individual measurements do not necessarily reflect the properties of the underlying tissue.

In the **Export** menu are buttons to download either the original source DICOM data, or the unannotated scan in DICOM or PNG format.

Results

The Results view shows the CT image after processing and analysis with e-CTA. The slices are annotated to show the vessel density, major vessels, arterial input location and venous output location, and any LVO that has been detected.

In the **Export** menu are buttons to:

- Download results and, if available, MIP images in PNG or DICOM format.
- Transfer the results to PACS over a DICOM network connection.
- Send the results to a remote system using peer-to-peer or cloud sync.
- Email the results to specific email addresses if configured.

In the **View** menu are buttons to:

- Change the scan reconstruction.
- If configured, multiplanar reconstructions (MPR) of the full CTA volume in different orientations can also be selected.
  - Axial, coronal and sagittal reconstructions are available
  - Administrators may configure the slab interval and slab thickness for each reconstruction
  - The slab interval defines the spacing between the start of each slab
  - The slab thickness defines the number of combined slices of the original image that are used for each slice on the MPR image
  - If slab thickness is greater than slab interval, then each slice in the MPR image will contain some data also present in adjacent slices (i.e. will overlap). If slab thickness is less than slab interval, then the output MPR will effectively have gaps and will not sample all of the input data.
- Change the layout, if available
- Reset zoom, to fit the whole scan into view.
- View the scan at 1:1 ratio

Scrolling through slices

To scroll through slices:

- On desktop computers, you can use your mouse wheel or hold down the left mouse button while moving the mouse up and down on the scan
- On touch devices, you can move one finger up and down on the scan (or use two fingers if the scan is zoomed).
- You can move the slider up and down.
- You can use the  and  buttons to change which slice is displayed

Windowing

Pixels in a CT scan are measured in Hounsfield Units (HU), which must be converted to grey levels for display. The windowing level and width controls in the **Windowing** menu allow you to adjust the range of HU values which are displayed.

These preset windows are provided to help you manually assess the scan:

- **Brain:** Provides a good overall view of brain tissue.
- **High-contrast:** Provides a high contrast view to make early hypodense changes more easily visible.
- **CTA:** Provides a better contrast to make enhanced vessels more easily visible.
- **Lung:** Good for viewing lung images.
- **Mediastinum:** Good for viewing soft tissue on chest CT.
- **CTPA:** Good for viewing pulmonary angiograms.
- **Bone:** Good for viewing bone structures.

You can add up to three custom windowing presets for your own use, which will be available in the same preset list.

Window width and level can also be adjusted by pressing and holding the middle mouse button over the viewer, while moving the mouse up/down (to change level) or left/right (to change width).

Overlays

Individual overlays shown on the Results view can be toggled on and off here. The overlay will only be listed if it is available for the current scan.

- **Vessel density:** Highlights areas where a lack of contrast has been detected.
- **Major vessels:** Colour-codes the large vessels supplying the brain.
- **Occlusion location:** Shows the point where an occluded vessel has been detected.
- **Arterial input function location:** Shows the voxels used to compute the arterial input contrast.
- **Venous output function location:** Shows the voxels used to compute the venous output contrast.
- **ASPECTS regions:** Shows the segmentation of ASPECTS regions.
- **pc-ASPECTS regions:** Shows the segmentation of pc-ASPECTS regions.
- **Mid-sagittal plane:** Toggles the mid-sagittal plane indicator line.
- **Text annotations:** Toggles the side indicators and other informational text overlays.

ASPECTS

ASPECTS (Alberta Stroke Program Early CT Score) is a topographic scoring system that divides the brain territory that is affected by the stroke into 10 areas of interest. There are six cortical regions (M1-M6), and four basal ganglia regions (caudate, lentiform, insula, and internal capsule). For each of the defined points, a single point is subtracted for an area of early ischemic change, such as parenchymal hypoattenuation. A score of zero indicates diffuse ischemic damage throughout the affected hemisphere, while a normal brain CT scan is assigned an ASPECTS of 10 points.

Note that the ASPECTS score, acute and non-acute ischemic changes in the ASPECTS regions are not computed by e-CTA.

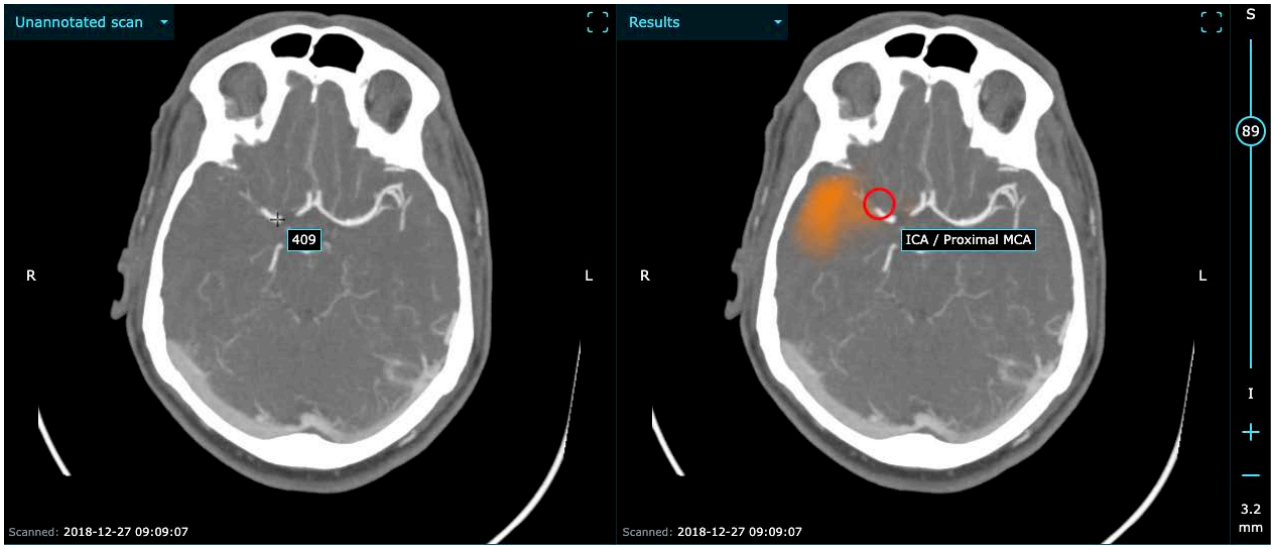
pc-ASPECTS

An additional scoring system for use in posterior circulation stroke is pc-ASPECTS (posterior-circulation ASPECTS) as defined in Puetz et al., Stroke, 2008 (https://doi.org/10.1161/STROKEAHA.107.511162) . It divides into 8 areas of interest: thalami (1 point each), occipital lobes (1 point each), midbrain (2 points), pons (2 points), cerebellar hemisphere (1 point each). A normal brain CT scan is assigned a pc-ASPECTS of 10 points.

Note that the pc-ASPECTS score, acute and non-acute ischemic changes in the pc-ASPECTS regions are not computed by e-CTA.

9.8 e-CTA Interactive Highlighting

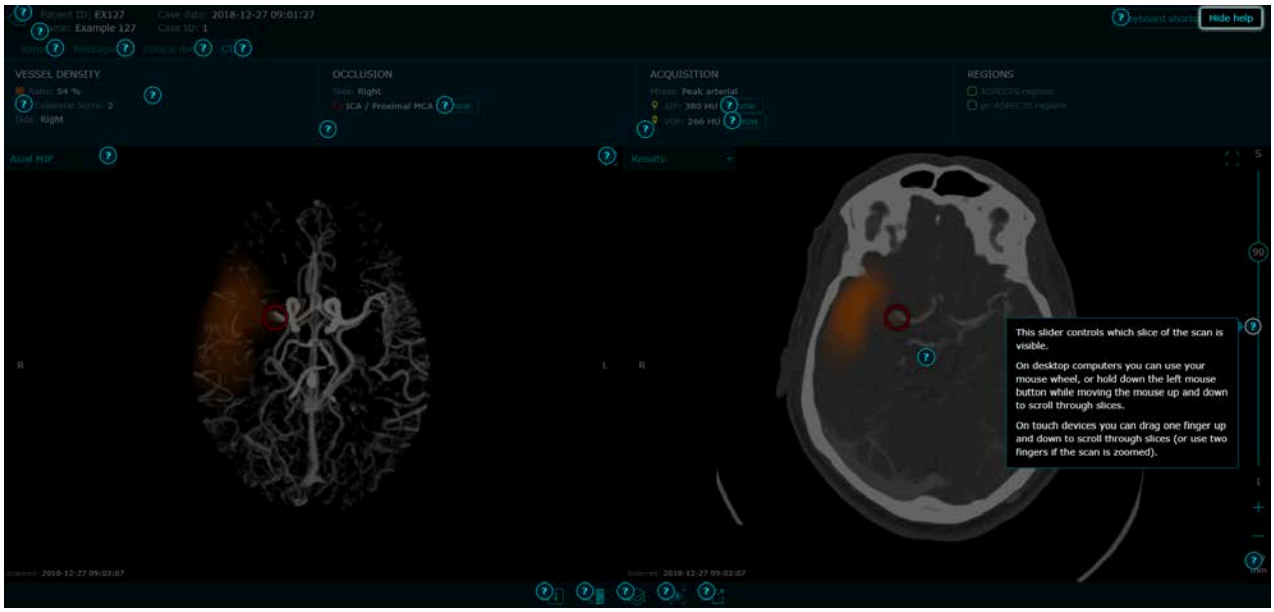
Moving the mouse pointer over the processed scan highlights vessels. Moving the mouse pointer over the original scan displays the HU value at that location.



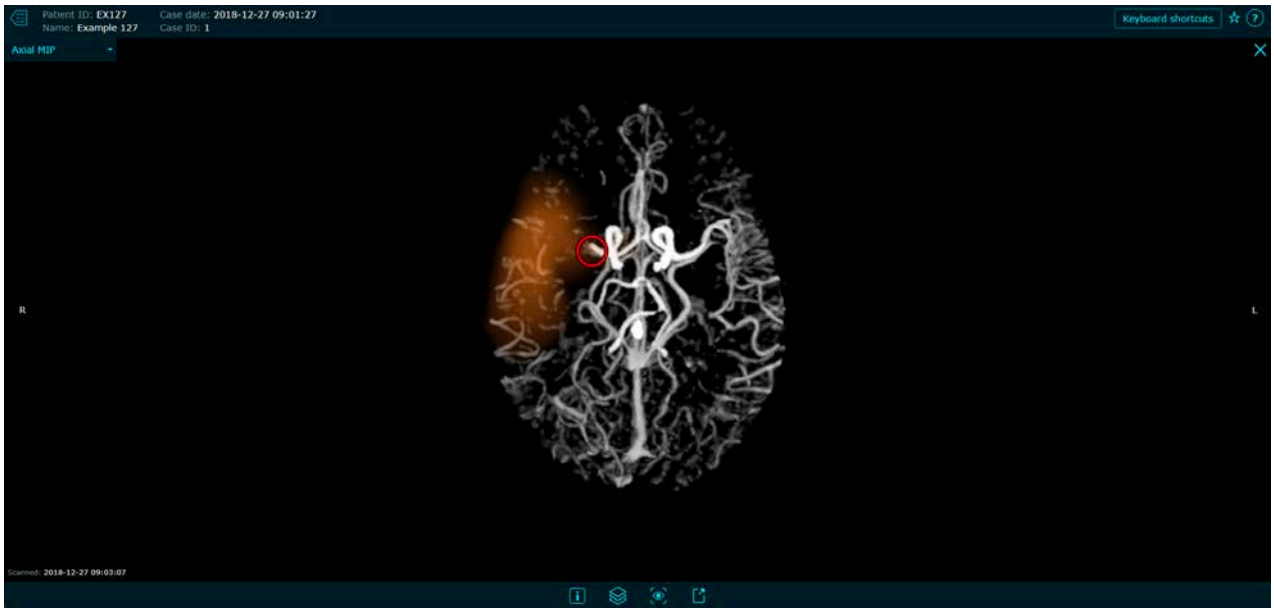
9.9 Help

The case viewer has a lot of functionality to aid in the assessment of the scans. You can access the help at any time by clicking the **Help** button. Each feature will be annotated with a button you can click to view the additional help. The additional help allows you to familiarize yourself with the controls and the various features available to you.

It is recommended that you view the help after major updates of the Brainomix 360 software to make yourself familiar with new features as they are added.



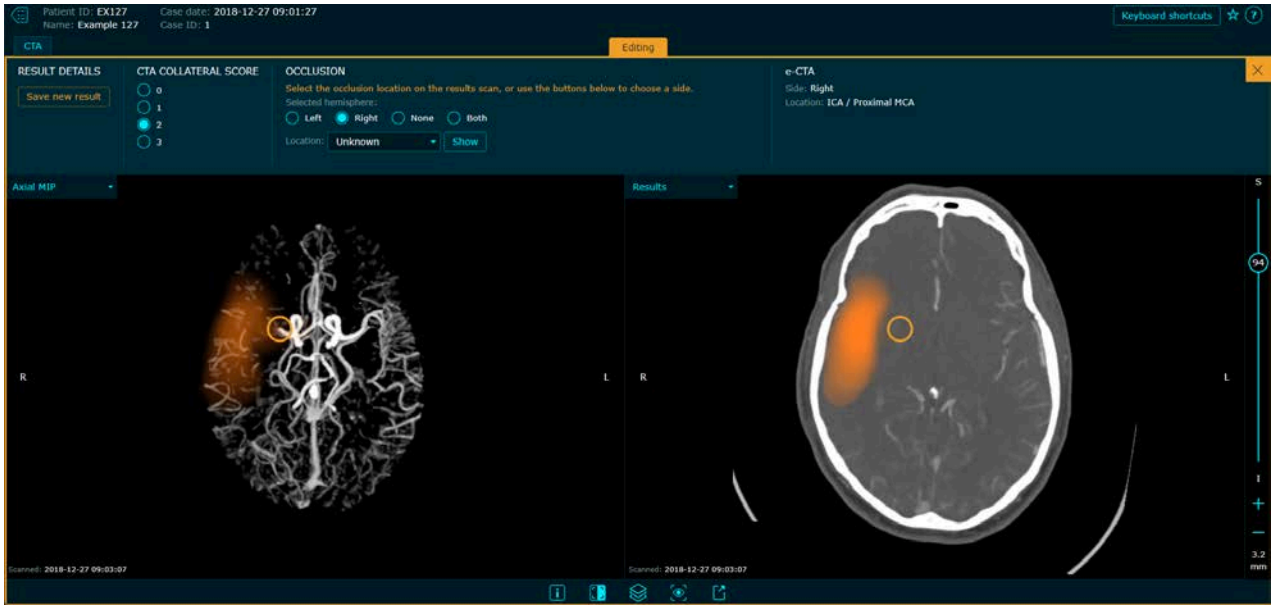
9.10 **Maximizing**



Any of the windows can be maximized to view them larger, one at a time. The relevant menus are available beneath the maximized window. Press X to return to the normal view.

9.11 **Manual results**

If enabled by your administrator, you can edit the automatic result and save your own manual result on Brainomix 360. This feature is not available when viewing cases on Brainomix 360 Cloud.



You can edit the automatic result by saving your own score. Click the 'Edit result' button to open the editing window.

Click the occlusion location on the scan, or select a side and vessel at the top. Select an option to change the CTA Collateral Score.

When saving your result, you can choose to publish it to any configured outputs, or just save it without publishing.

9.12 Sharing cases

If enabled by your administrator, you can share a pseudonymized case with someone inside or outside your organisation with a sharing link.

To create a sharing link:

- Click on the "Share case" button in the case viewer. Note that this button is not displayed if sharing has not been enabled.
- When the link is displayed, click "Copy URL to clipboard".
- Paste the link into an email or messaging app.

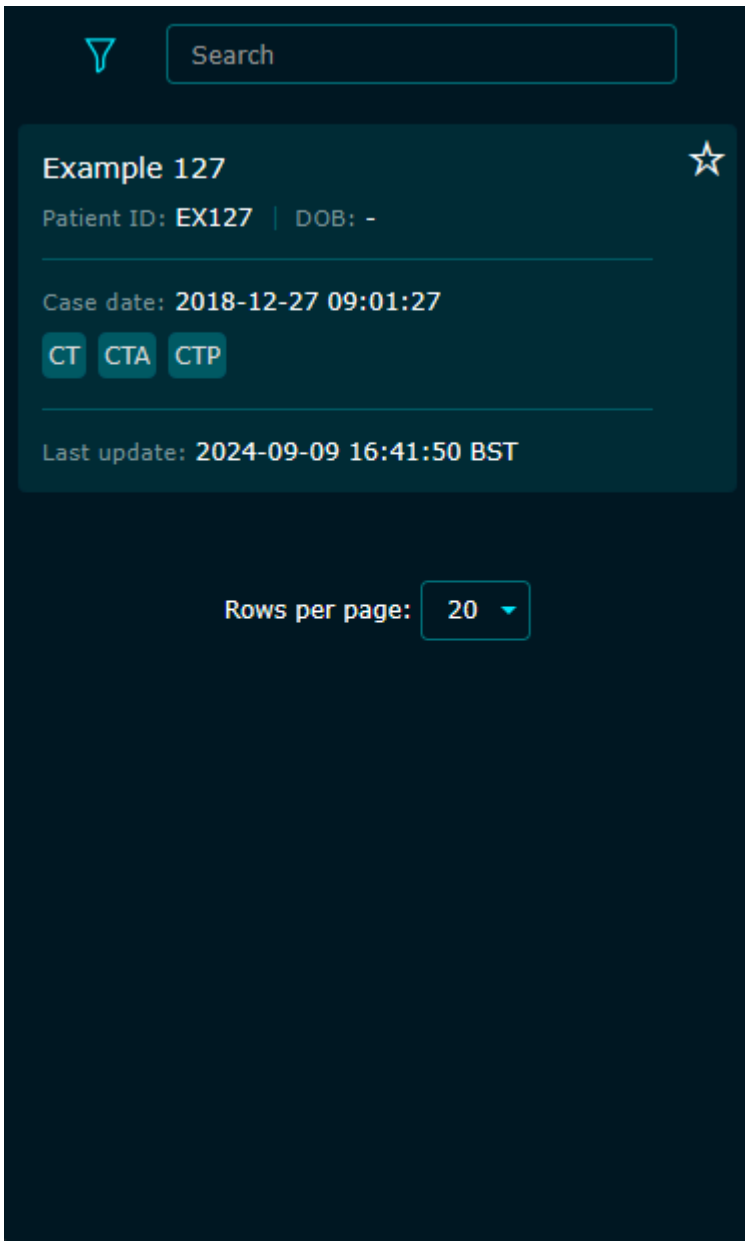
Important Notes on Sharing Links

- Opening the shared link will give access to all scans in one case only.
- The link will be pseudonymized so the recipient will not be able to see any personally identifying information in the case viewer.
- The recipient must have network access to the server if it is on an intranet.
- Anyone with the link can access the pseudonymized case until the link expires. The expiry time is configurable by your administrator.

10 Mobile Display

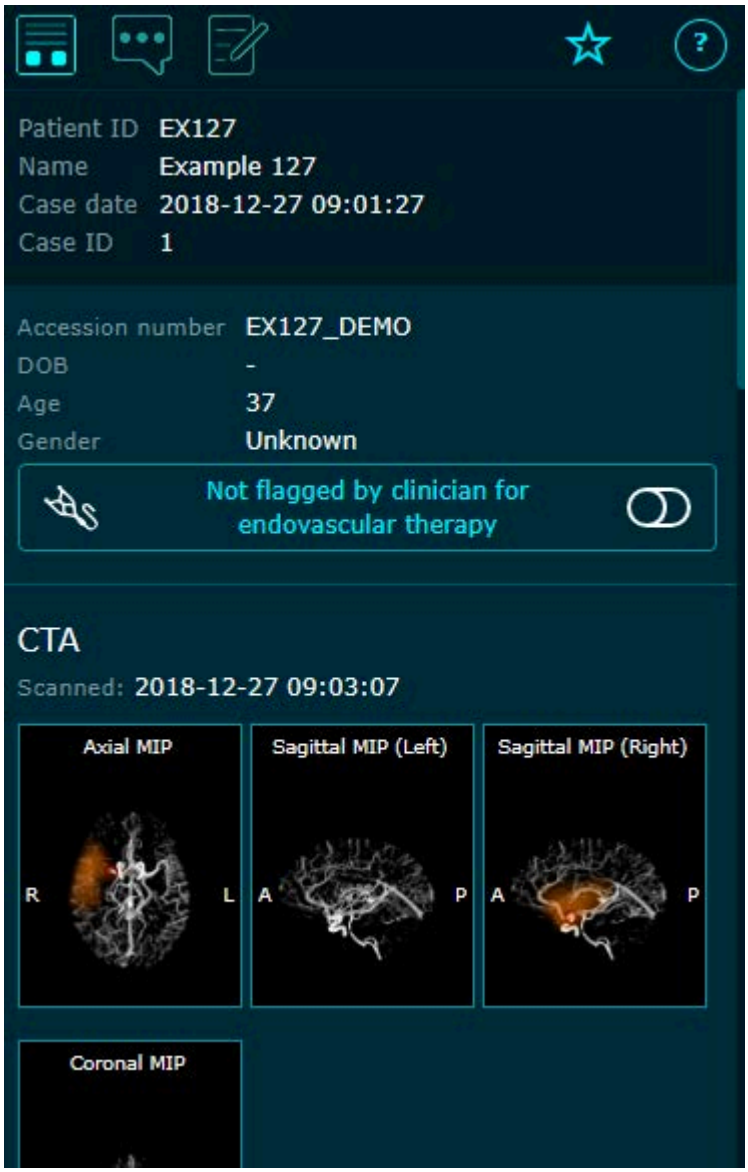
10.1 Cases List

If you access Brainomix 360 or Brainomix 360 Cloud using your phone, you can view a list of all the cases. Tap a case to open it. Swiping down will refresh the case list.



10.2 Report

You can view the full case report of all imaging modalities and open each scan individually to scroll through slices and view all scan and result information from the report.



10.3 **Scan Viewer**

In the viewer you can scroll through all scan slices by dragging one finger up and down on the scan (or use two fingers if the scan is zoomed), or by using the bar at the side.

The metadata for this scan, and all results from e-CTA are available within the buttons at the bottom of the viewer.

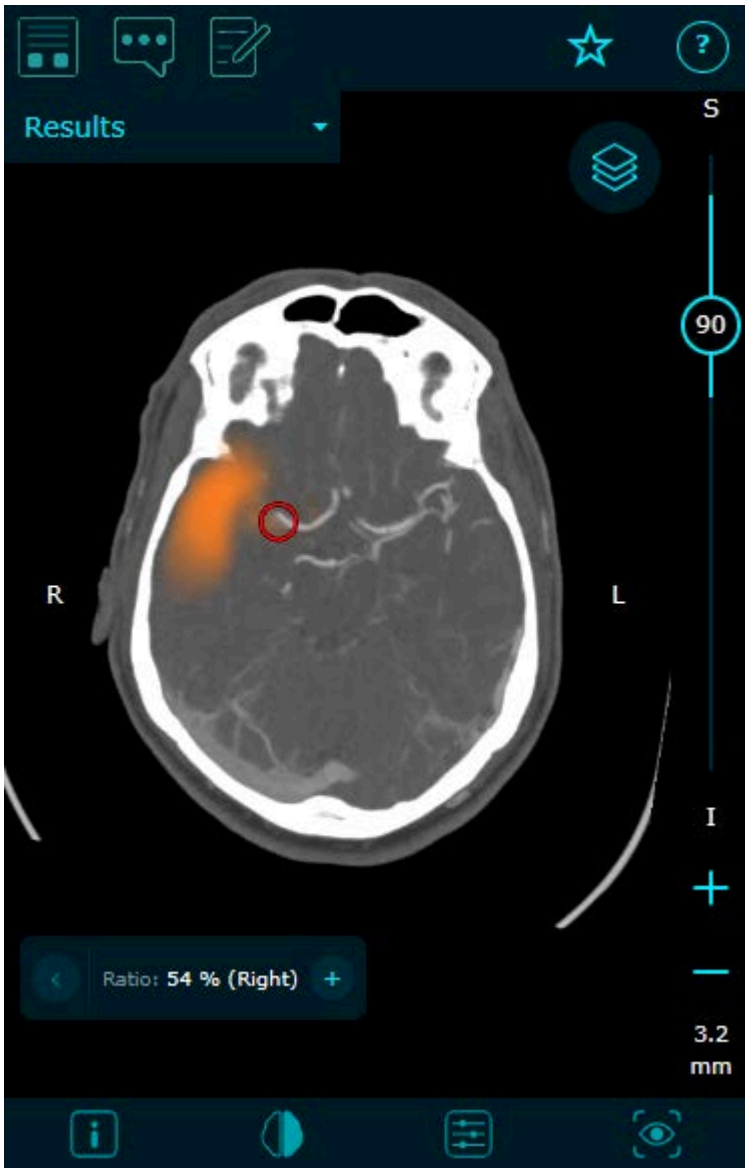
You can change the windowing using the preset windows and toggle the overlays on or off.

You can also press and hold the scan to toggle overlays on or off.

Using pinch-to-zoom, you can zoom the scan to see it in more detail and you can move it around by dragging it.

Tap the active button at the bottom of the screen to close that control and view the scan in full screen mode.

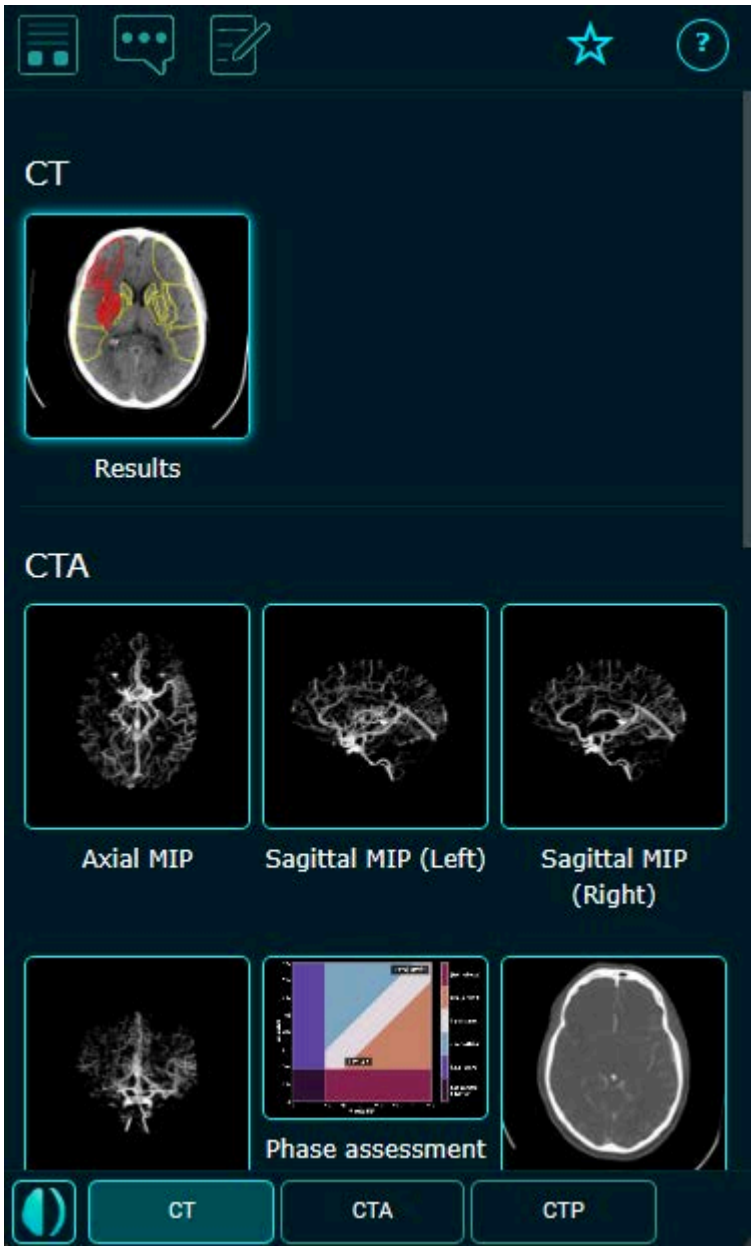

Axial MIP
R
L
Ratio: 54 % (Right)



10.4 **Menu**

Tap the Brainomix button in the bottom left corner to open the Brainomix menu. You can see all the scans in this case, and navigate to any available view by tapping the thumbnail.

Alternatively, you can use the modality drawer at the bottom to go directly to the results view of a scan. To expand the tray tap on the button on the bottom right, tap it again to close the tray.



10.5 Sharing cases

If enabled by your administrator, you can share a pseudonymized case with someone inside or outside your organisation with a sharing link.

To create a sharing link:

- Click on the  button in the case viewer. Note that this button is not displayed if sharing has not been enabled.
- The link is displayed. On Android or iOS devices, click "Share URL" to share directly with another app.
- Alternatively, click "Copy URL to clipboard" then paste the link into an email or messaging app

Important Notes on Sharing Links

- Opening the shared link will give access to all scans in one case only.
- The link will be pseudonymized so the recipient will not be able to see any personally identifying information in the case viewer.
- The recipient must have network access to the server if it is on an intranet.

- Anyone with the link can access the pseudonymized case until the link expires. The expiry time is configurable by your administrator.

11 Result Outputs

11.1 DICOM

If configured at your site, result DICOM series will be transferred to PACS over a DICOM network connection once processing has finished.

11.2 Email Notifications

If configured at your site, email notifications containing results will be sent to configured email addresses once processing has finished.

11.3 Case Reports

If configured at your site, case report PDFs containing an overview of all imaging modalities and results for a patient will be sent to configured email addresses and/or to PACS over a DICOM network connection.

11.4 Peer-to-Peer Sync

If configured at your site, full results will be synchronised to remote Brainomix 360 installations with optional pseudonymization. At the remote site, the results can be viewed as if the scan had been processed there.

11.5 Cloud Sync

If configured at your site, full results will be synchronised to the Brainomix 360 Cloud service with optional pseudonymization. Results can be viewed on Brainomix 360 Cloud as if the scan had been processed there.

11.6 Mobile App Notifications

If sync with Brainomix 360 Cloud is enabled, push notifications can be configured to notify users of the Brainomix 360 Mobile app that a result is available.

12 Uploading and Processing

This section applies only to Brainomix 360. It is not possible to upload or process scans directly on Brainomix 360 Cloud.

12.1 Processing Scans

Workflows

Brainomix 360 can be configured to provide different workflows for use in the acute clinical pathway or for clinical studies. Each workflow can be configured to send email notifications or results to different addresses and to different target DICOM devices.

Two default sets of workflows are supplied, "Acute" and "Study". The acute workflows are intended to process a small number of scans with high priority, while the study workflows are suited to processing large numbers of lower priority scans. If a scan is being processed by a study workflow when an acute scan is received, Brainomix 360 will pause it and process the acute scan before continuing.

For assistance in configuring your workflows and integration with external systems (PACS, CT scanners, email etc.), contact your local distributor or Brainomix support.

Manual DICOM Transfer

1. Ensure the source DICOM device (e.g. PACS or CT scanner) and the controlling application (e.g. PACS viewer) are configured with the Brainomix 360 server address and Application Entity Title for the appropriate Brainomix 360 incoming scan queue linked to the desired workflows (see above). Your system administrator should be able to help you configure these.
2. Use the controlling DICOM application to transfer a scan series to the Brainomix 360 server. Refer to the application’s instructions for more information.
3. The Brainomix 360 server will automatically begin processing the series.
4. To monitor processing in your web browser:
    1. Go to the Brainomix 360 server address in your internet browser
    2. You will be prompted to log in if you have not used the application recently from your current web browser. Log in as described in the previous section.
    3. Select **Case List** from the menu bar at the top of the page.
    4. The new scan should appear in the case list. If it does not, consult the DICOM log to check for errors.
5. If configured, results emails will be sent out and DICOM results will be sent to PACS automatically when processing is completed. Use your regular email client or PACS viewer to see these results.
6. Alternatively, click on the case in the case list to view the results in your web browser.

Automatic DICOM Transfer

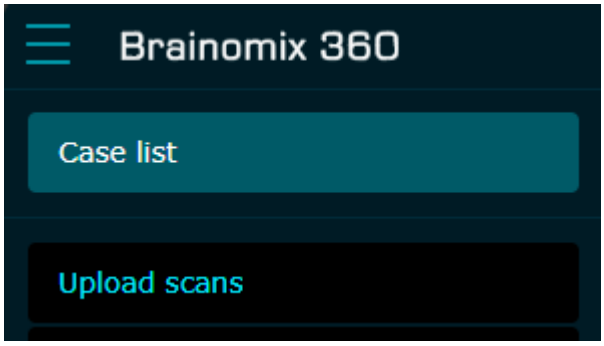
An external application may be configured to automatically transfer scan series to the Brainomix 360 server.

If configured, results emails will be sent out and DICOM results will be sent to PACS automatically when processing is completed. Use your regular email client or PACS viewer to see these results. In this configuration you do not need to use the Brainomix 360 web interface at all.

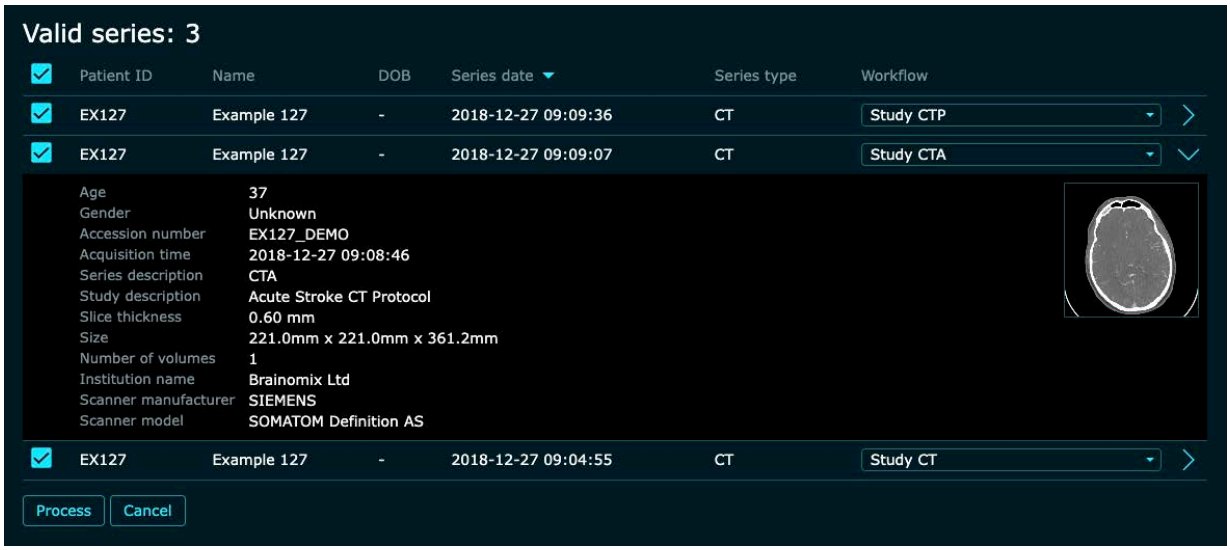
Alternatively, log in and the cases will appear in the case list as soon as they are queued for processing. Results can be viewed by clicking on a case. The DICOM network activity can be monitored by viewing the DICOM log.

Manual Upload via Web Interface

1. Log in to Brainomix 360
2. Open the menu using the menu icon at the top of the page.
3. Select **Upload Scans** from the menu.



4. Select the appropriate incoming scan queue from the drop-down menu below the upload area. This setting will be set to use the study incoming scan queue by default.
5. Click **Upload** to select DICOM image files or compressed zip files containing DICOM images.
   Tip: You can drag and drop files directly onto the upload area if the browser supports drag and drop.
   Note: If you select too many files the browser will reject them. If this occurs, you should compress the DICOM images into a single zip file and upload that instead.
6. Your files will be uploaded and indexed. If there are a very large number of files this may take several minutes.
7. A preview of the files that you have uploaded is displayed once they have been indexed. Series which cannot be processed will be listed separately as invalid series, and any files which are not DICOM images will be listed in the ignored files section.

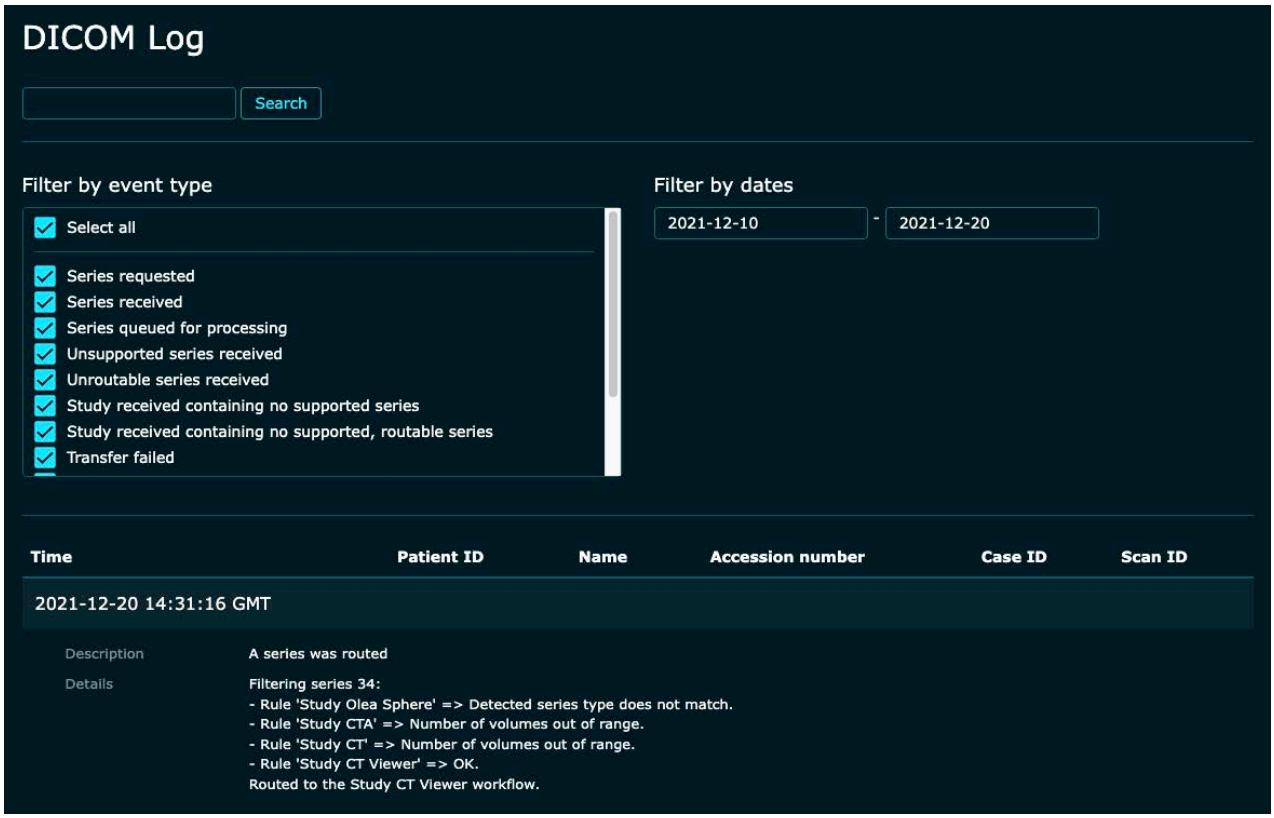


8. Click on the ⌄ icon to expand the patient and scan details and to see a preview thumbnail of the scan.
9. By default, all scans which can be routed to a workflow are marked to be processed. If there are scans that you do not wish to have processed by Brainomix 360, then deselect them by clearing their tick-boxes. You may also override the workflow selection by choosing from the options displayed in the workflow column.
10. When you are happy that the files you want to process are correct, click on the **Process** button. If you do not wish to continue, click **Cancel**.
11. Once the processing has begun, the case list page will be displayed.

12. When processing completes, results emails and DICOM results will be sent automatically as configured for the workflow.
13. Click on the scan in the scan list to view the results in your web browser.

12.2 The DICOM log

Click on the "DICOM log" link to view a log of DICOM series requested, received and sent by the Brainomix 360 server.



13 Administration

Administrator users have extra features available to them for managing users, deleting scans and configuring the integration of the Brainomix 360 system into the clinical workflow. In general, these settings will not need to be changed and incorrect settings may result in data loss, incorrect operation or compromised security. If you require assistance with the integration of your Brainomix 360 system into your clinical workflow, please contact your local distributor or Brainomix support.

14 Troubleshooting

In case of any issues encountered during use or if presented with any error messages, contact your local administrator or Brainomix support at one of the contact options indicated in the Regulatory Information section.

15 Service Maintenance and Upgrades

In the event of a planned maintenance, Brainomix will inform impacted users in advance that maintenance work is being carried out and what level of interruption to service is expected. User access may be denied during the maintenance window. If the Brainomix 360 Mobile app is installed on a mobile device, ensure to update to the latest version when prompted or made available on the Google Play or the Apple App Store.

16 Incident Reporting

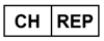
Please contact us via support@brainomix.com (mailto:support@brainomix.com) if you have discovered a potential issue with any of our Brainomix 360 suite services. Note that any information you submit will be governed by our Privacy Policy (https://www.brainomix.com/privacy-eu/#:~:text=For%20users%20of%20Brainomix%20products,in%20order%20to%20provide%20support). If a serious incident has occurred in relation to any of our products, please also report it to the local competent authority of your country:

- Member States of the European Union (https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human)
- United Kingdom of Great Britain and Northern Ireland (https://www.gov.uk/report-problem-medicine-medical-device)
- Switzerland (https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/users---operators.html)
- Turkey (https://www.titck.gov.tr/)

17 Decommissioning

In the event of discontinuation and removal of service, Brainomix will coordinate the process with the relevant stakeholders at your organization to ensure smooth and complete removal of the Brainomix 360 system, including any assets and data. The impact of removal will be assessed to determine whether it will result in changes to your clinical workflow and/or the configuration of other systems. Any assets owned by Brainomix will be reclaimed and integrations will be removed from the system to ensure there is no more data transfer taking place to or from the to be decommissioned asset(s). For more information on the process of decommissioning of your Brainomix 360 system, please contact your local distributor or Brainomix support.

18 Symbols

Symbol	Description of symbol
	Indicates the medical device manufacturer's name and address.
	Indicates the date when the medical device was manufactured.
	Indicates the carrier that contains unique device identifier information.
	Indicates the authorized representative in the European Community.
	Indicates the authorized representative in Switzerland.
	Indicates the entity importing the medical device into the locale.
	Indicates the need for the user to consult the instructions for use.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Indicates the item is a medical device.
	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information.
	CE marking indicates that a product complies with the applicable European Union regulations.

19 Request a Paper Copy

Should you require a printed hard copy of this revision of the user manual of Brainomix 360 e-CTA, please consider printing out this webpage (right click + Print or download the latest revision from our website (https://www.brainomix.com/docs/)). If this option is not available for you, please contact us via support@brainomix.com (mailto:support@brainomix.com) with your request and a printed copy will be sent to you within 7 calendar days of the receipt of request. This service is provided free of charge.